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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,298	07/02/2003	Byron E. Anderson	45240-105719	5133

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EXAMINER	
GROSS, CHRISTOPHER M	
ART UNIT	PAPER NUMBER
1639	

NOTIFICATION DATE	DELIVERY MODE
04/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/612,298	ANDERSON, BYRON E.	
	Examiner	Art Unit	
	CHRISTOPHER M. GROSS	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,44,46 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,44,46,50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responsive to communications entered 12/9/2008. Claims 5, 44, 46, and 50 are pending. Claims 5, 44, 46, 50 are examined herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/9/2008 has been entered.

Priority

The present application was filed 7/2/2003. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is acknowledged. This application claims benefit of provisional application(s): 60/394,176 filed 07/03/2002.

Withdrawn Rejection(s)

The rejection of claims 5, 44, and 46 to 48 under 35 U.S.C. 103(a) as being unpatentable over **Momany** (EP 00180072) in view of **Barany et al** (US Patent 5235028) is hereby withdrawn in view of applicant's amendments.

The rejection of claims 5, 44, 46, 49, 50 and 47 under 35 U.S.C. 103(a) as being unpatentable over **Dooley** (WO 94/26296 – IDS entry 5/6/2008) in view of **Barany et al** (US Patent 5235028) is hereby withdrawn in view of applicant's amendments.

Maintained Claim Rejection(s) - 35 USC § 112

Claims 5,44,46,51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection concerns new matter.

Response to Arguments

On p 13 of the remarks entered 12/9/2008 argument asserts, to the best the examiner understands, that the libraries set forth in the application inherently have at least 68% of the D-peptides consisting of at least three aromatic amino acid residues. In this vein, it is noted that according to paragraph 0015, suitably, about 30% or more of the D-peptides comprise three or more aromatic D-amino acid residues; still more suitably, 40% or even as many as 50% or more of the D-peptides comprise at least three or more aromatic D-amino acid residues. Notably the above passage recies enrichments of aromatic amino acids outside the range of 68-100% (i.e. at least 68%) set forth in claim 5.

New Claim Rejection(s) – 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 50 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection concerns new matter

Please note that this claim was previously not rejected under 35 USC 112 first paragraph concerning new matter, however upon further analysis the following is noted.

Claim 5 from which claim 50 depends includes the limitation wherein at least 68% of the D-peptides consist of at least three aromatic amino acid residues.

On p 3 of the remarks entered 6/27/2008, applicant argues that 68% of the pentapeptide library set forth in paragraph of the present specification inherently contains 68 % at least three aromatic amino acid residues. While the examiner finds support for a D-pentapeptide library containing 68% three or more D-Tyr, D-Phe or D-Trp residues in paragraph 0016, the examiner does not find support for the broader recitation aromatic amino acids, which would include D isomers of non naturally occurring amino acids for instance, as set forth in claim 5.

As mentioned above, the specification as originally filed provided no implicit or explicit support for at least 68% of the D-pentapeptides consist of at least three aromatic amino acid residues.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes “If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02

teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure*.

Claim 5,44,46,50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether undue experiment is necessitated. These factors can include, but are not limited to:

(1) the breadth of the claims;
(2) the nature of the invention;
(3) the state of the prior art;
(4) the relative skill of those in the art;

(5) the level of predictability in the art;
(6) the amount of direction provided by the inventor;
(7) the existence of working examples; and
(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1 and 2) The breadth of the claims and the nature of the invention: The invention is drawn to a combinatorial library including D-peptides linked to a support so that the D-peptides are **soluble**.

(3 and 5) The state of the prior art and the level of predictability in the art: Solid phase peptide synthesis, developed by R.B. Merrifield (1963 JACS 85:2149-2154) is a predictable method of synthesizing peptides known in the art which allows handily removal of reagents and by-products by filtration. According to Merrifield, in the sentence bridging the right and left columns the reason the approach [works] is the growing peptide chain is firmly attached to a completely **insoluble** solid particle. Merrifield discusses the technical difficulties (i.e. unpredictability) associated with classical (i.e. solution) phase peptide synthesis in the first paragraph on p 2149.

(4) The level of one or ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in this art, *given its unpredictability*, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6 and 7) The amount of direction provided by the inventor and the existence of working examples:

On pp 12-13 of the present specification, applicant applies split synthesis, a variation or Merrifield solid phase synthesis, popularized by Lam et al (1991 Nature 354: 82-84 PTO 892 7/2/2006) toward the synthesis of a D-peptide library. Merrifield solid phase peptide synthesis, requires the growing peptide chain be insoluble. Accordingly, applicant has not provided any working examples of peptides linked to a support yet are soluble.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The amount of experimentation necessary make and use the invention is considerable because the combinatorial library made in the disclosure utilizes Merrifield solid phase peptide synthesis which requires growing peptide chains to be insoluble, yet the combinatorial library claimed is drawn to soluble peptides. Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, undue experimentation would be required of one of skill in the art to practice the claimed invention.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation "the solid support" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1639